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| In re Application of | : |
| Siemeister et al | : |
| Serial No.: 10/796174 | :DECISION ON PETITION |
| Filed: 10 March 2004 | : |
| Attorney Docket No.: SCH-1815-C1 | : |

This letter is in response to the Petition filed under 37 C.F.R. 1.144 filed on 17 August 2009 requesting review and withdrawal of restriction requirement mailed 20 April 2006.

**BACKGROUND**

This application was filed as a national application under 35 U.S.C. 111 and as such is subject to US restriction practice.

On 20 April 2006, the examiner mailed a restriction requirement in which claims 1-22 were divided into 3 groups, as follows;

> Group I, claims 1-7 and 9-11 drawn to a composition comprising two specific compounds.
> Group II, claim 8, drawn to a composition comprising one compound.
> Group III, claims 22 drawn to a method of using the composition for treatment.

Group I and II were then further divided into two groups depending upon whether the compound inhibited or activated VEGF/VEGF and/or receptor systems. The examiner required an election of species amongst

i) a small molecular weight substance
ii) polynucleotides
iii) an oligonucleotide
iv) antisense oligonucleotide
v) an oligopeptide
vi) a recombinant protein
vii) an antibody
viii) a single chain antibody
ix) a conjugate or fusion protein of any one of the above

The examiner also required an election of one or two compounds from the following list:

a) any one (1) of SEQ ID NOS: 1-60 (claims 12 and 13)

b) (4-Chlorophenyl)[4-(4-pyridylmethyl)-phthalazin-1-yl]ammonium hydrogen succinate (or another specific small molecular weight molecule, which must be identified by name) (claims 15-18)

c) sTie2 (claims 14 and 17-21)

d) mAB 4301-42-35 (claims 14, 17-20)

e) scFv-tTF (claims 14, 17-21)

f) L19 scFv-tTF conjugate (claims 14, 17, 18)

The examiner reasoned that Groups I and II were unrelated. The examiner reasoned that the product and process Groups were distinct because cancer could be treated by radiation. The examiner also required an election of a single disease encompassed by Claim 22.

On 18 July 2006, applicant elected, with traverse, Group I and the species of small molecular weight substances that inhibit or interfere with VEGF/VEGF and/or receptor systems.

On 2 November 2006, the examiner considered the traversal. The examiner maintained the restriction requirement, however, removed (which is being interpreted here as withdrew) the election of species requirements for the purposes of examining all pending claim. The examiner incorrectly indicated that Claims 8 and 12-22 were cancelled. (Instead, claims 8 and 12-22 were withdrawn from consideration as being directed to non-elected subject matter.) Claims 1-7 and 9-11 were rejected as follows:

Claims 1-7 were rejected under 35 USC 112, first paragraph for lack of adequate written description.

Claims 1-7 and 9-11 were rejected under 35 USC 103(a) as being obvious over Thorpe.

On 2 May 2007, applicant filed a response to the Office action.

On 20 September 2007, in a final Office action, claims 8 and 12-22 were withdrawn from consideration as being directed to non-elected inventions. Claims 1-2, 4-7 and 9-11 were rejected under 35 USC 103(a) as being obvious over Thorpe.

On 20 March 2008, applicants filed a request for continued examination along with an amendment to the claims, which added new claims 23-24. It is noted that claim 24 was directed to elected Group I and is limited to the elected species.

> **Claim 23. (New)** A method of treating a tumor or tumor metastasis in a subject, comprising administering into said subject an effective amount of the pharmaceutical composition of claim 1.
>
> **Claim 24. (New)** The pharmaceutical composition of claim 1 wherein compound I is 4-Chlorophenyl)[4-(4-pyridylmethyl)-phthalazin-1-yl]ammonium hydrogen succinate and compound II is sTie2.

On 10 June 2008, the examiner mailed a non-final Office action in which claims 8 and 12-24 were withdrawn from consideration as being directed to non-elected inventions. Claims 1-2, 4-7 and 9-11 were rejected under 35 USC 103(a) as being obvious over Thorpe.

On 10 December 2008, applicant filed a response to the Office action.

On 17 March 2009, the examiner mailed a final Office action in which claims 8 and 12-24 were withdrawn from consideration as being directed to non-elected inventions. Claims 1-2, 4-7 and 9-11 were rejected under 35 USC 103(a) as being obvious over Thorpe.

On 9 February 2009, applicants filed this petition under consideration along with a Notice of Appeal.

## DISCUSSION

The petition and file history have been carefully considered.

Before turning to the merits of the petition, it is noted that the inventions of Group I and II are not unrelated. Rather the compositions of Claim 8 (Group II) are generic to and thereby encompasses the compositions of Group I.

MPEP 806.03 states:

> Where the claims of an application define the same essential characteristics of a single disclosed embodiment of an invention, restriction therebetween should never be required. This is because the claims are not directed to distinct inventions; rather they are different definitions of the same disclosed subject matter, varying in breadth or scope of definition.

Moreover, MPEP 806 states:

C) Where inventions are related as disclosed but are not distinct as claimed, restriction is never proper.

For these reasons, the restriction required between Group I and II was improper because the groups are not distinct.

The petition requests withdrawal of the restriction requirement for claims 14-18 and 24. Claims 14-18 and 24, along with claims 12-13 and 19-21 depend from independent Claim 1 and differs in scope by reciting varying subgenera or species encompassed by the generic Claim 1. Because the election of species requirements were withdrawn in the first office action on the merits, these claims must be examined with the generic claims.

Moreover, it is noted that several of the dependent claims which had been withdrawn from examination actually recite the elected species. This is improper. The examiner cannot refuse to examine applicants elected invention.

Finally, the petition requests that withdrawn claims 22-23 be rejoined for examination.

Withdrawn claims 22-23 are directed to method of using the elected product. MPEP 821.04(b) provides guidance that when all claims to the elected product are in condition for allowance, process claims which depend from or otherwise require all the limitations of a allowable product be considered fro rejoinder. Because the product claims are currently under rejection, any request for rejoinder at this time is premature.

For these reasons, the Office action mailed 7 November 2008 was incomplete.

**DECISION**

The petition is **GRANTED-IN-PART** for the reasons set forth above.

The finality of the Office action mailed November 2008 has been withdrawn.

The restriction requirement between Group I and II has been withdrawn.

The restriction requirement between the products (Groups I/II) and processes (Group III) is maintained, because not all claims to the elected product are in condition for allowance.

It is noted that the election of species requirements were withdrawn in the first Office action on the merits.

All claims directed to the composition (claims 1-2, 4-21 and 24) will be examined together on the merits.

**The application will be forwarded to the examiner for preparation of an Office action consistent with this decision, and following the guidelines for rejoinder of process claims per MPEP 821.04(b).**

Should there be any questions about this decision, please contact Quality Assurance Specialist Julie Burke, by letter addressed to Director, Technology Center 1600, at the address listed above, or by telephone at 571-272-0512 or by facsimile sent to the general Office facsimile number, 571-273-8300.

John LeGuyader
Director, Technology Center 1600